STATE OF TENNESSEE
COMPTROLLER OF THE TREASURY

BOARD OF PHARMACY AND CONTROLLED SUBSTANCE DATABASE COMMITTEE

Performance Audit Report

October 2015

Justin P. Wilson, Comptroller

Division of State Audit
Sunset Performance Section

DEBORAH V. LOVELESS, CPA, CGFM, CGMA
Director

JOSEPH SCHUSSLER, CPA, CGFM
Assistant Director

SANDRA TULLOSS
Audit Manager

Lisa Williams, CGFM, CFE
In-Charge Auditor

Mike Huffaker
Jaclyn Clute
Staff Auditors

Amy Brack
Editor

Amanda Adams
Assistant Editor

Comptroller of the Treasury, Division of State Audit
Suite 1500, James K. Polk State Office Building
505 Deaderick St.
Nashville, TN 37243-1402
(615) 401-7897

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STATE OF TENNESSEE
COMPTROLLER OF THE TREASURY
DEPARTMENT OF AUDIT
DIVISION OF STATE AUDIT
SUITE 1500, JAMES K. POLK STATE OFFICE BUILDING
505 DEADERICK STREET
NASHVILLE, TENNESSEE 37243-1402

PHONE (615) 401-7897
FAX (615) 532-2765

October 20, 2015

The Honorable Ron Ramsey
Speaker of the Senate
The Honorable Beth Harwell
Speaker of the House of Representatives
The Honorable Mike Bell, Chair
Senate Committee on Government Operations
The Honorable Jeremy Faison, Chair
House Committee on Government Operations
and
Members of the General Assembly
State Capitol
Nashville, Tennessee 37243
and
Dr. Reginald Dilliard, Executive Director
Board of Pharmacy
665 Mainstream Dr.
Nashville, TN 37243

Ladies and Gentlemen:

Transmitted herewith is the sunset performance audit of the Board of Pharmacy and Controlled Substance Database Committee. This audit was conducted pursuant to the requirements of the Tennessee Governmental Entity Review Law, Section 4-29-111, *Tennessee Code Annotated*.

This report is intended to assist the Joint Government Operations Committee in its review to determine whether the board and committee should be continued, restructured, or terminated.

Sincerely,

Deborah V. Loveless

Deborah V. Loveless, CPA
Director

15015

State of Tennessee

Audit Highlights

Comptroller of the Treasury Division of State Audit

Performance Audit
Board of Pharmacy
and
Controlled Substance Database Committee
October 2015

We have audited the Board of Pharmacy and Controlled Substance Database Committee for the period January 2, 2011, through December 31, 2014. Our objectives were to

- determine if there are exceptions to the statutory per diem reimbursement for board members and the reason for such exceptions;
- determine if the board meets the Department of Health's internal benchmarks for processing initial licenses for pharmacists (120 days); initial licenses for pharmacies, pharmacy technicians, manufacturers, wholesalers, distributors, researchers, and drug dog handlers (100 days); and renewal licenses for all (14 days);
- determine the extent to which the board is monitoring disciplined licensees, and the board's relationship with and use of the Tennessee Pharmacists Recovery Network and similar entities (if any) to monitor disciplined licensees with potential substance abuse or similar issues;
- determine whether the board's inspectors are completing inspections within the Health Related Boards' self-imposed guidelines and whether those guidelines are appropriate and need to be formalized;
- determine the timeliness of the disciplinary process resulting from inspection findings;
- identify any statutory and structural gaps in the Controlled Substance Database monitoring program that potentially limit the database's effectiveness;
- determine the extent to which the database is analyzed and queried to proactively provide information to regulatory boards and law enforcement;

- determine if appropriate platform, application, and data controls are in place and regularly monitored for the database;
- determine if the board has sufficient authority to pass legal and investigative costs on to the disciplined licensee, and if so, the extent to which it consistently does so;
- evaluate the board's expenses in recent fiscal years and its ability to remain self-sufficient as required by state law;
- determine if board operations, meetings, and membership meet key statutory requirements and are consistent with other best practices;
- determine whether the board's licensee continuing education is adequately monitored, especially in light of the 2009 audit finding regarding the Health Related Boards' continuing education monitoring; and
- gather basic background information about the board and database, including their priority performance measures.

For our sample design, we used nonstatistical audit sampling, which was the most appropriate and cost-effective method for concluding on our audit objectives. Based on our professional judgment, review of authoritative sampling guidance, and careful consideration of underlying statistical concepts, we believe that nonstatistical sampling provides sufficient, appropriate audit evidence to support the conclusions in our report. We present more detailed information about our methodologies in the individual report sections.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

AUDIT FINDINGS

While the Board of Pharmacy issues its licenses in a timely manner, with the exception of pharmacist licenses, the Health Related Boards' computer system could not track and monitor the licensing process to identify impediments

The Health Related Boards' (HRBs) outdated computer system, the Regulatory Board System (RBS), has continued to inhibit the accurate tracking of the timeliness of the licensing process. The HRBs were waiting to take corrective action until the implementation of a replacement computer system. We found that between January 2, 2011, and December 31, 2014, the Board of Pharmacy was meeting its licensing benchmarks for all license types except pharmacists. The HRBs replaced RBS with LARS (the Licensing and Regulatory System) on April 20, 2015. According to staff, the new system cannot identify delays in the licensing process (page 6).

The Board of Pharmacy does not monitor disciplined licensees; has no formal, written policies and procedures for doing so; and has no formal relationship with its recommended peer assistance recovery network

Though the Department of Health stated, in response to the previous audit finding regarding the lack of disciplinary policies and monitoring, that it was adding a monitoring component to its disciplinary action database that would be incorporated in its new computer system, we found that the board still has not developed procedures regarding its disciplinary monitoring practices, is not monitoring disciplined licensees, and has no disciplinary action database (page 11).

Statutory and structural gaps may limit the effectiveness of the Controlled Substance Database monitoring program and the information it provides

Statutory exemptions to reporting information to the database and checking the database before writing or filling a prescription results in an incomplete picture of all medications dispensed and virtually allows medical and pharmacy professions to police themselves. Additionally, structural gaps including lack of oversight and enforcement regarding exemptions mean that noncompliance is usually discovered by accident (page 16).

Staff of the Controlled Substance Database monitoring program and the Department of Health do not proactively analyze the database to provide information to health regulatory boards and law enforcement

Statute requires the Controlled Substance Database Committee to examine the database to identify unusually high patterns and to refer pharmacists or prescribers to Board of Pharmacy or Health Related Boards' investigators. The committee is also required to use the database to assist in research, statistical analysis, criminal investigations, enforcement of state and federal laws involving controlled substances, and the education of healthcare practitioners. However, staff only prepare an annual "Top 50 Prescribers" list of those writing prescriptions for the highest amounts of opioids and benzodiazepines and an annual report to the General Assembly of the aggregate prescribing and dispensing trends. Program staff do not search for unusual prescribing or dispensing patterns, but they do make referrals to the Bureau of Investigations or Pharmacy Board investigators if they inadvertently find suspicious activity (page 19).

Program staff and the Department of Health do not monitor the vendor that provides and maintains the Controlled Substance Database for compliance with contract requirements regarding data controls for ensuring validity and reliability, though it appears the vendor does have such controls in place

In 2011, the Department of Health entered into a contract with Optimum Technology, Inc., to provide the information technology service that would be the database for the Controlled Substance Database monitoring program. Though the contractor appears to provide the detailed security work required by contract, neither monitoring program staff nor Department of Health staff monitor the contractor's compliance with the contractual requirements (page 21).

The Board of Pharmacy has no written policies or procedures for licensing, inspection, investigations, or the imposition of disciplinary actions and penalties that ensure staff and board members conduct business in a timely, consistent, and equitable manner

There are no operational policies and procedures detailing how the Board of Pharmacy will fulfill its statutory duties and how staff are to fulfill day-to-day duties (page 22).

Conflict-of-interest disclosure statements should be filed annually as required by the Health Related Boards' regulations and best practices

Health Related Boards' Policy 302.01 requires board members to sign the conflict-of-interest policy upon being appointed to the board and annually thereafter. We reviewed all available conflict-of-interest disclosure statements for board members who served during fiscal years 2010 through 2014. We found that (1) the Health Related Boards' staff stated some of the oldest forms were lost, and (2) the current board members had only filed one disclosure statement since the annual requirement went into effect in 2012 (page 24).

OBSERVATIONS

The audit also discusses the following issues: Board of Pharmacy staff established guidelines in 2013 for conducting inspections on a more frequent basis (page 8); there is no minority member of the Board of Pharmacy as intended by statute (page 25); the Board of Pharmacy is not properly including required statements of necessity in meeting minutes and is not filing such statements with the Secretary of State when, to achieve a quorum, members are allowed to tele-participate in meetings (page 25); the Board of Pharmacy may wish to require those requesting waivers to be present at the hearing or available by telephone, as it often has questions that require further communication with that individual or entity (page 26); and to address its lack of self-sufficiency in fiscal year 2014, the Board of Pharmacy raised fees and implemented, along with the Office of General Counsel, the recovery of legal costs (page 26).

Performance Audit
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INTRODUCTION

PURPOSE AND AUTHORITY FOR THE AUDIT

This performance audit of the Board of Pharmacy and Controlled Substance Database Committee (until 2012, the Controlled Substance Database Advisory Committee) was conducted pursuant to the Tennessee Governmental Entity Review Law, *Tennessee Code Annotated*, Title 4, Chapter 29. Under Section 4-29-237, the board and the committee are scheduled to terminate June 30, 2016. The Comptroller of the Treasury is authorized under Section 4-29-111 to conduct a limited program review audit of the agencies and to report to the Joint Government Operations Committee of the General Assembly. The audit is intended to aid the Joint Government Operations Committee in determining whether the Board of Pharmacy and the Controlled Substance Database Committee should be continued, restructured, or terminated.

HISTORY AND ORGANIZATION

Board of Pharmacy

Created by Section 63-10-301 et seq., *Tennessee Code Annotated*, the Board of Pharmacy consists of seven members, one of whom is a consumer, appointed by the Governor for one non-repeatable six-year term. The Governor appoints the members of the board from graduates of a recognized school or college of pharmacy, ensuring that at least one person serving on the board is 60 years of age or older and that one is a member of a racial minority. Pharmacists must have lived and practiced at least five years in Tennessee to be eligible for nomination to the board. The consumer member must also have lived in the state for at least five years and have no financial or other interest in a healthcare facility or business. The Governor may remove members for misconduct at the recommendation of the remaining board members. Board members receive a per diem of $100 a day for attending board meetings and other administrative functions of the board, as well as the necessary travel expenses.

Controlled Substance Database Committee

Created by Section 53-10-303, *Tennessee Code Annotated*, the Controlled Substance Database Committee, previously an "advisory" committee only until that was changed by amendment effective January 1, 2013, consists of the following 14 members:

1. Executive Director – Board of Pharmacy, who serves as database manager

2. Director of the Health Related Boards
3. Executive Director – Board of Medical Examiners
4. Governor-appointed, licensed member – Board of Medical Examiners
5. Governor-appointed, licensed member – Board of Osteopathic Examination
6. Governor-appointed, licensed member – Board of Dentistry
7. Governor-appointed, licensed member – Board of Registration in Podiatry
8. Governor-appointed, licensed member – Optometry Board
9. Governor-appointed, licensed member – Board of Veterinary Medical Examiners
10. Governor-appointed, licensed member – Board of Nursing
11. Governor-appointed, licensed member – Board of Medical Examiners' Committee for Physician Assistants
12. Governor-appointed, licensed member – Board of Pharmacy
13. Public member – Board of Pharmacy
14. Public member – Board of Medical Examiners

The committee must meet at least annually and as often as deemed necessary either at the call of the chair or upon the request of at least three members. A quorum for official action is composed of seven members. The members of the committee are considered to be performing official duties as members of their original board or committee and are entitled to the same per diem and travel reimbursements as they would receive for performing their duties for their original board or committee. The member's original board or committee pays for the per diems and travel reimbursements.

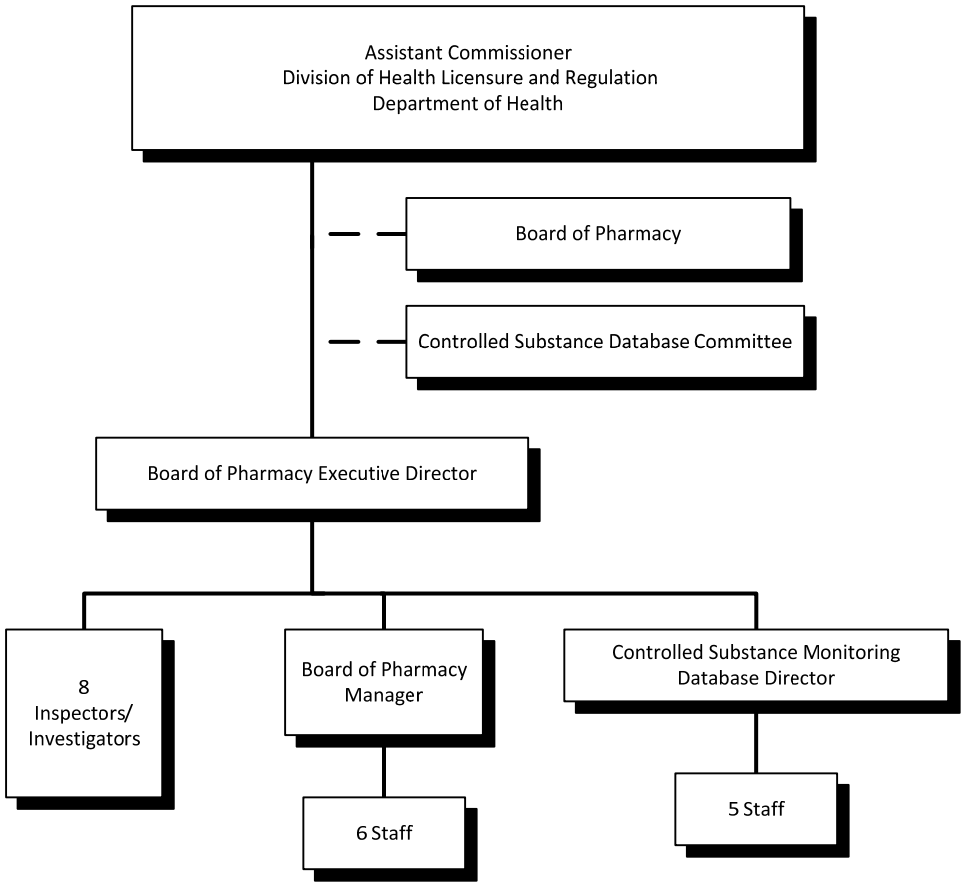
AUDIT SCOPE

We audited the Board of Pharmacy's activities for the period January 1, 2011, through December 31, 2014. Our audit scope included a review of internal controls and compliance with laws and regulations that are significant within the context of the audit objectives. Management of the Board of Pharmacy is responsible for establishing and maintaining effective internal controls and for complying with applicable laws, regulations, and provisions of contracts and grant agreements.

For our sample design, we used nonstatistical audit sampling, which was the most appropriate and cost-effective method for concluding on our audit objectives. Based on our professional judgment, review of authoritative sampling guidance, and careful consideration of underlying statistical concepts, we believe that nonstatistical sampling provides sufficient, appropriate audit evidence to support the conclusions in our report. We present more detailed information about our methodologies in the individual report sections.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Board of Pharmacy
Controlled Substance Database Committee
Organization Chart
May 2015



PRIOR AUDIT FINDINGS

The Board of Pharmacy (board) has resolved the finding from the 2009 sunset performance audit regarding querying the National Practitioner Data Bank by requiring that applicants for reciprocity use the National Association of Boards of Pharmacy's Licensure Transfer Program. This program performs a background check of the transfer applicant's license and screens it through the association's clearinghouse and the National Practitioner Data Bank.

The board has also resolved the December 2009 sunset performance audit finding that the board's continuing education audit process was inconsistent and lacked documentation. The board has integrated its process, as recommended, with the Health Related Boards' consistent and well-documented process that was preexisting. We found that board staff are effectively performing continuing education audits.

OBJECTIVES, METHODOLOGIES, AND CONCLUSIONS

BOARD OF PHARMACY

Section 63-10-304 through 307, *Tennessee Code Annotated*, requires the Board of Pharmacy (board) to enforce the laws pertaining to

- the practice of pharmacy;
- the manufacture, distribution or sale of drugs; and
- the medication use process, including, but not limited to compounding, selection, preparation/production, dispensing/distribution, patient administration, education and monitoring of drugs, devices, chemicals or poisons.

The Division of Health Licensure and Regulation employs for the board the necessary administrative and clerical staff to carry out the board's duty to enforce pharmaceutical laws. Administrative staff to the board consist of an executive director, board manager, six staff, and eight pharmacist inspectors/investigators. The pharmacist investigators are authorized to "conduct inspections of pharmacies and any other site where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed, or administered." The investigators can conduct investigations of any board licensee and of any unlicensed activity. The board issues and oversees licenses for

- pharmacists,
- pharmacies,

- pharmacy technicians,
- manufacturers/wholesalers/distributors,
- researchers, and
- medical service representatives.

The board also

- enacts rules addressing professional conduct and standards of practice to ensure competent pharmaceutical care;
- inspects any site or professional pharmacy practice where drugs, medicines, chemicals, pharmaceuticals, or poisons are manufactured, stored, sold, dispensed, distributed or administered;
- determines the competency of graduates of recognized schools or colleges of pharmacy applying for licensure;
- ensures compliance with pharmacy law; and
- takes disciplinary action and conducts hearings when appropriate.

Licenses and Inspections

In the December 2009 sunset performance audit, we found that the Health Related Boards (HRBs) needed better methods and information to monitor its licensing timeliness, and that its outdated computer system (Regulatory Board System – RBS) inhibited accurate monitoring and tracking of the timeliness of the licensing process. The Department of Health's six-month follow-up report in August 2010 stated the HRBs were waiting to take corrective action until after it had selected and implemented an RBS replacement computer system in the near future. The HRBs implemented its Licensure and Regulatory System (LARS), the replacement for RBS, five years later on April 20, 2015.

Our audit objective was to determine if the Board of Pharmacy (board) was meeting the HRBs' internal benchmarks for processing the various licenses the board issues. As established by the HRBs, the board's benchmarks are 120 days for processing pharmacist licensure applications and 100 days for processing licensure applications for pharmacy technicians; pharmacies; manufacturers, wholesalers, and distributors; and researchers and drug dog handlers.

We obtained data on initial and renewed licenses and determined that the board was generally meeting its timeliness benchmarks, with the exception of pharmacist licenses. (See finding 1 below.)

We also had as our objective to determine whether the board's inspectors were completing inspections within the board's self-imposed guidelines of

- sterile compounders – every 12 months,

- pharmacies – every 18 months, and
- manufacturers/wholesalers/distributors – every 24 months.

We compared the board's informal guidelines with facility inspection dates between January 1, 2011, and December 31, 2014, as recorded in RBS.

To assess data reliability, we reviewed a random sample of 25 of 2,939 facilities to determine whether the inspection information keyed into RBS by board staff matched the information contained in the original paper inspection form. We could locate only 21 of 25 files' original inspection paperwork in the form of scanned or paper documents. RBS and the original documents matched in 20 files and one file's date was off by one day.

Our review showed that the board's inspectors/investigators significantly increased the number and timeliness of inspections they conducted, missing fewer benchmark inspection opportunities on all facility types in the latter half of our audit period compared to the earlier half.

Finding

1. While the Board of Pharmacy issues its licenses in a timely manner, with the exception of pharmacist licenses, the Health Related Boards' computer system could not track and monitor the licensing process to identify impediments

We reviewed the board's licensing process, benchmarks, and RBS reports for January 1, 2011, through December 31, 2014. Ultimately, we reviewed all initial and renewed license types from January 1, 2013, through December 31, 2014, to determine the extent to which the board met its license processing benchmarks. Our review identified only one issue—23% of initial pharmacist licenses (356 of 1,561) took longer than 120 days to process.

Timeliness Monitoring

HRB management sets benchmarks, and compiles for the Assistant Commissioner a semi-annual average licensing timeliness report on all health related boards. This report, however, is not shared with any of the boards except to address staffing matters and employee performance. We reviewed 12 of 16 semi-annual licensing reports for the board from January 1, 2011, through December 31, 2014. The complete reports for calendar years 2013 and 2014 did not indicate any issue with licensing timeliness with the exception of pharmacist applications. However, the board is not provided these reports.

We also questioned the reliability of these semi-annual reports. To determine whether data in RBS matched the information in original paper applications for licensure, we reviewed a random sample of 40 out of 7,629 initial licenses issued between January 1, 2011, and December 31, 2014. We confirmed that RBS data matched the information contained on the original initial paper applications for licensure. However, RBS licensing reports are problematic because they can produce duplicate information. Duplicates occur because an applicant or licensee's

application/license process may stop and start for a variety of reasons, resulting in multiple initial licensing dates associated with one license issuance date. HRB management requires board staff to review and correct the raw data and provide explanations for license processing delays from each RBS semi-annual report before management creates the final averaged semi-annual report submitted to the director of the HRBs.

RBS also does not provide the reason for delays in processing. To determine whether delays were caused by the applicant or caused by board staff, we reviewed the processing time for all pharmacist licenses issued between January 1, 2013, and December 31, 2014, and then performed a case study of the 30 that took the longest time to process. Of the 30 applications we reviewed, for 24 (80%) the delays were caused by the applicants. Some of the most common applicant-caused delays included failed exams, nonpayment of fees or returned checks, and missing application materials that led to incomplete and expired applications. Of the remaining six files reviewed, four (13.3%) were not initial applications but license reinstatements that had been incorrectly pulled by RBS because of the duplicate date problem mentioned previously. The remaining two files (6.7%) were delays caused by board staff. An additional observation was that 24 (80%) of the applications reviewed had to go through National Association of Boards of Pharmacy Licensure Transfer Program processing before submission to the board as they were transfers of licenses from other states.

New Computer System Implemented

Over the course of the audit, the HRBs' long-awaited new computer system, LARS, was implemented. This computer system was in the early stages of development during the HRBs' 2009 performance audit. Although several licensing issues identified in the 2009 audit have been addressed, LARS currently does not have the capability to identify delays in the licensing process. As a result, it remains difficult to determine whether board staff process applications as quickly as possible.

Recommendation

The Board of Pharmacy should work with the Commissioner of the Department of Health to improve the Health Related Boards' new computer system, LARS, to include the ability to track each step of the licensing process so that the Board of Pharmacy can control staff-caused delays in the licensing process.

Management's Comment

We concur. While the audit found that only two applications were delayed by board staff, we feel that further steps can be taken to ensure that no such delays occur in the future. With the implementation of LARS (Licensure and Regulation System) in April of 2015, we expect to eliminate the duplication of information that occurred in the former RBS (Regulatory Board System). Additionally, the Department is working on a Phase 2 for LARS which will

include online applications and the ability of staff and the applicant to monitor progress of an application through licensure.

Observation

1. Board of Pharmacy staff established guidelines in 2013 for conducting inspections on a more frequent basis

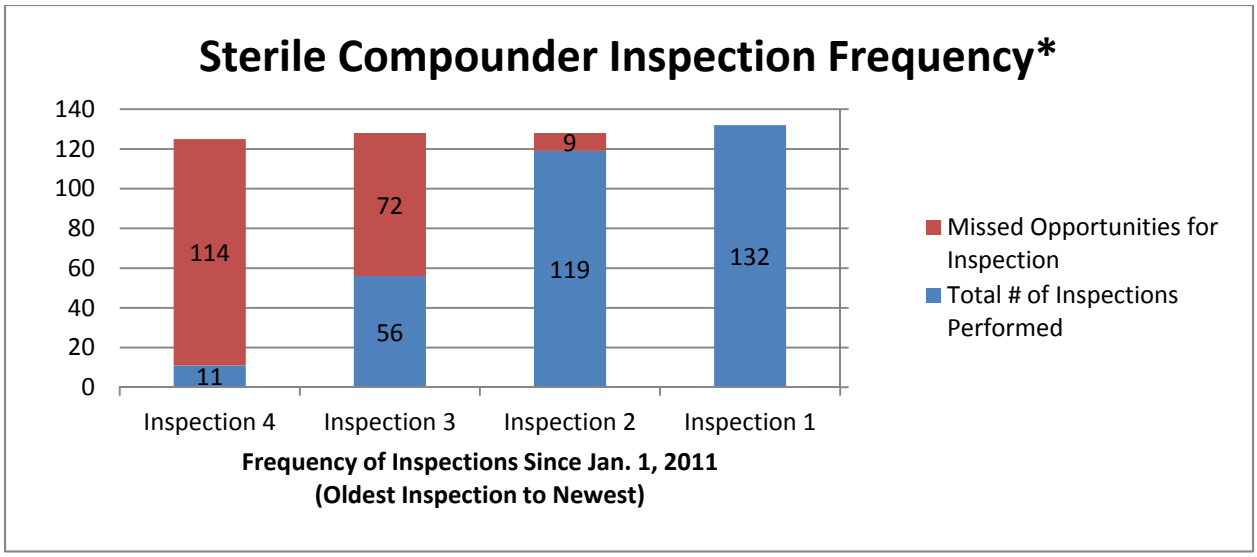
While inspections are not a statutory requirement for licensure of in-state pharmacies, manufacturers, wholesalers, distributors, and sterile compounders in Tennessee and many of its surrounding states, in 2013 Tennessee's Board of Pharmacy (board) adopted informal guidelines that are similar and a little more frequent than those recommended by the National Association of Boards of Pharmacy (NABP). The board's inspection guidelines are the following:

- pharmacies – once every 18 months (NABP – 24 months),
- manufacturers/wholesalers/distributors – once every 24 months (NABP – 36 months), and
- sterile compounders – once every 12 months (NABP – same).

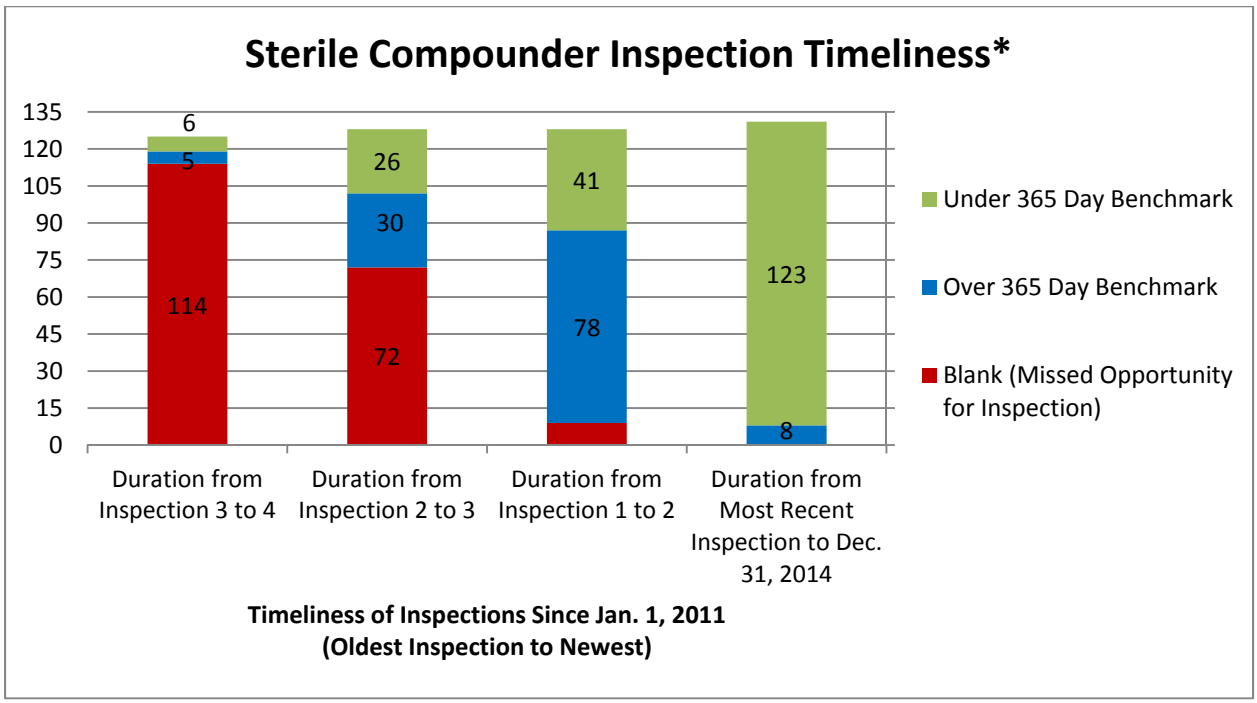
At the same time in 2013, in light of events involving an outbreak of fungal meningitis that claimed 64 lives (16 in Tennessee) and sickened 751 people, the board sent out a facility-wide survey to identify all sterile compounding facilities in the state and began a sterile compounder tracking and inspection program.

We obtained the dates of all inspections conducted between January 1, 2011, and December 31, 2014, on the 2,939 pharmacies, manufacturers, wholesalers, distributors, and in-state sterile compounders whose licenses were active during that period. To determine whether board inspectors were meeting internal inspection benchmarks, we calculated (1) the number of inspections and opportunities for inspections for each facility and (2) the duration of time between each inspection for all 132 in-state sterile compounders and a random sample of 25 of all other facilities (no sterile compounders happened to fall out in the sample). An "opportunity for inspection" is a time period during which an inspection could have been done to meet the guidelines. For example, a sterile compounding facility was inspected on January 12, 2011; August 2, 2012; and January 16, 2014. This facility had the opportunity to be inspected in 2013 but was not, so pharmacy investigators made three out of four possible inspections of that facility. The duration of time between each inspection was 568 days and 532 days, respectively, so pharmacy investigators did not meet their benchmark of once every 12 months (365 days).

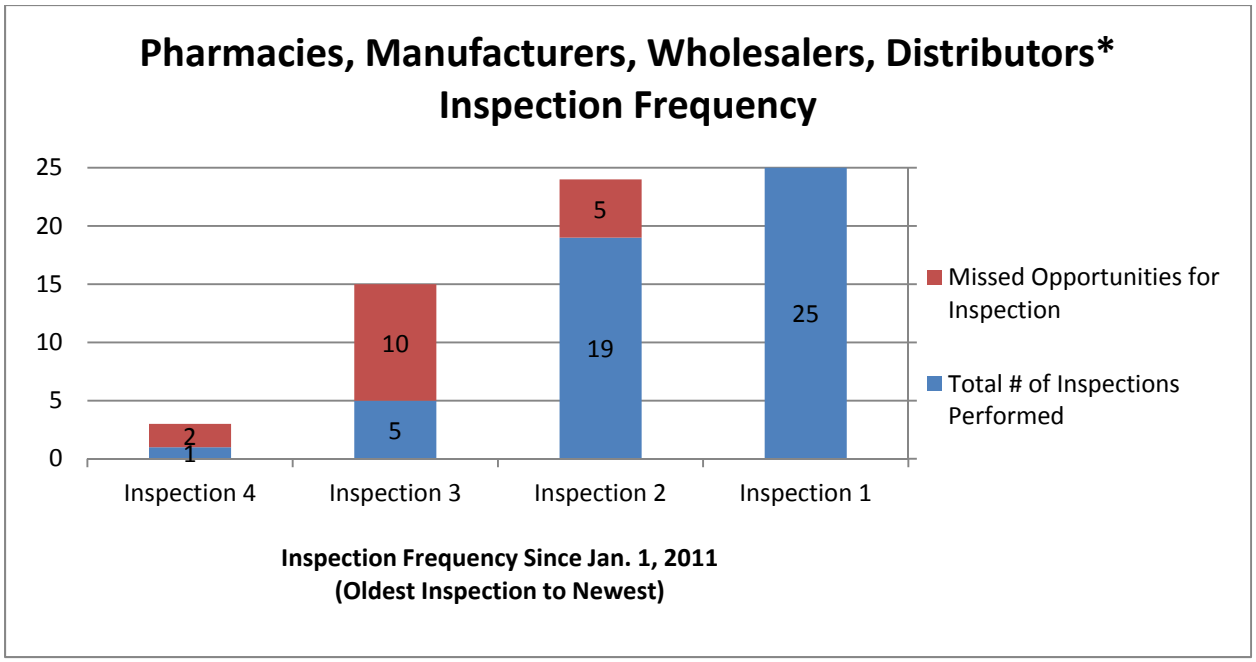
Our review showed that the board's inspectors/investigators significantly increased the number and timeliness of inspections they conducted, missing fewer benchmark inspection opportunities on all facility types in the latter half of our audit period compared to the earlier half.



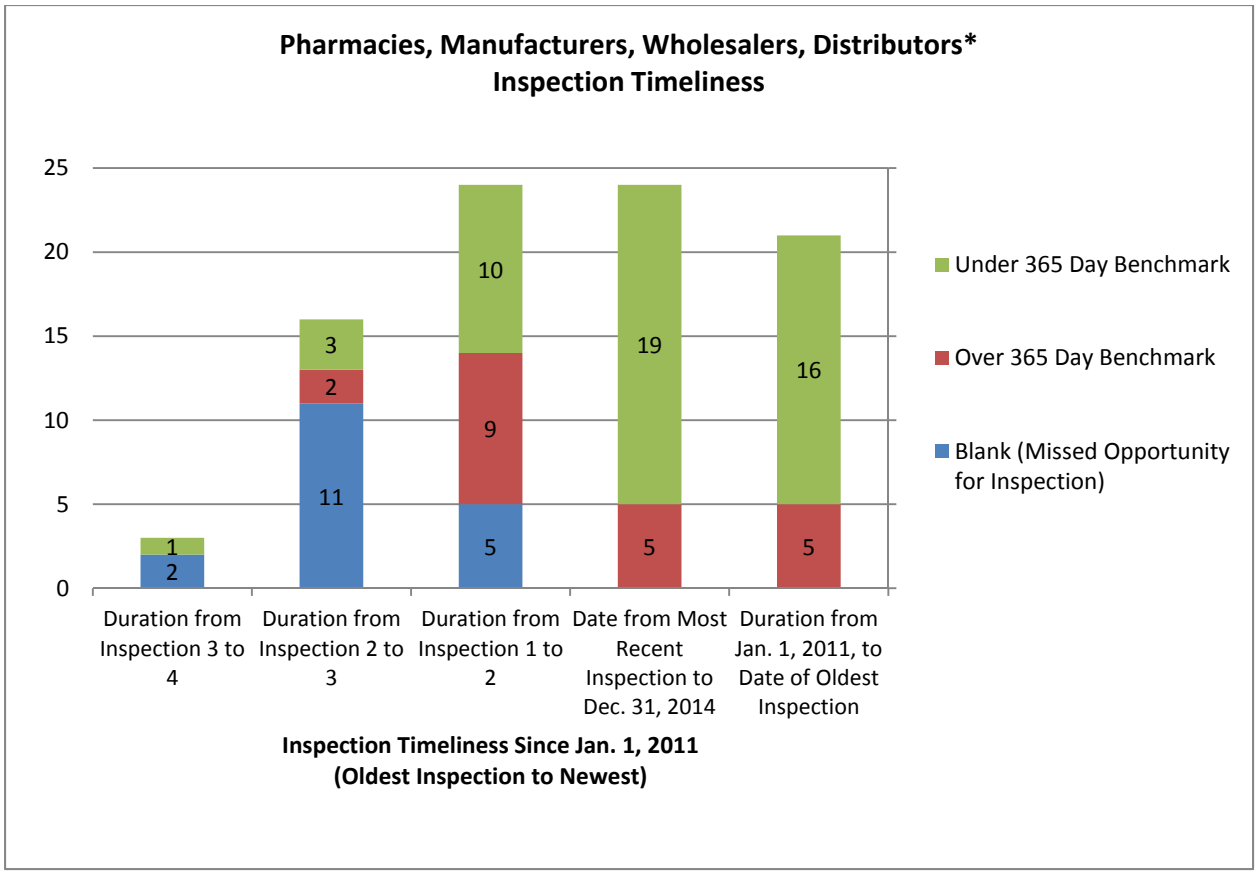
*Numbers may not total 132 as the number of inspections required depends on a facility's licensure date.



*Numbers may not total 132 as the number of inspections required depends on a facility's licensure date.



*Numbers may not total 25 as the number of inspections required depends on a facility's licensure date.



*Numbers may not total 25 as the number of inspections required depends on a facility's licensure date.

Pharmaceutical facilities that are not inspected on a regular basis have the potential to adversely affect the health and wellness of the citizens of Tennessee. The board's informal guidelines for inspecting pharmacies, manufacturers, wholesalers, and distributors have only been the standard since 2013 and future reviews of inspection timeliness will determine whether the program is providing sufficient oversight. The Board of Pharmacy should formalize its guidelines regarding inspection frequency into formal, written policy, procedures, and rules. The addition of three new inspectors/investigators in late 2013 should aid the board in meeting the guidelines.

Disciplinary Action Monitoring

At the time of the December 2009 Health Related Boards' (HRBs) performance audit, the Board of Pharmacy (board) did not have formal, written procedures regarding its disciplinary monitoring practices and relied on peer assistance programs to monitor participants. The Department of Health commented that the board was in the process of adding a monitoring component to its existing disciplinary action database. At the time of the audit's six-month follow-up report in August of 2010, the Department of Health stated that the board had developed a manual disciplinary monitoring process and the disciplinary action database would be incorporated in the Regulatory Board System's (RBS) replacement system.

Our audit objectives were to determine

- the extent to which the board is monitoring disciplined licensees, and
- the board's relation to and use of the Tennessee Pharmacists Recovery Network and similar entities (if any) to monitor disciplined licensees with potential substance abuse or similar issues.

We found the board still has not developed formal, written procedures regarding its disciplinary monitoring practices. The board's administrative manager, who is the disciplinary coordinator, states she and board staff do not monitor disciplined licensees and she is unaware of the existence of a disciplinary action database.

Finding

2. The Board of Pharmacy does not monitor disciplined licensees; has no formal, written policies and procedures for doing so; and has no formal relationship with its recommended peer assistance recovery network

Despite maintaining the record of disciplinary actions taken against licensees, the board and its staff do not actively monitor a licensee for compliance with the terms of the board's disciplinary decision while it is in force and has no policies to do so. The board disciplines licensees through a variety of methods such as fines, probation, requirements to successfully complete a chemical dependency recovery program, and license suspension and revocation.

During calendar years 2013 and 2014, the board dealt with 751 allegations brought before it for disciplinary action.

Tennessee Pharmacist Recovery Network

The Tennessee Pharmacists Association (TPA) and its Tennessee Pharmacists Recovery Network (TPRN) have a long-standing relationship with the Board of Pharmacy, though no formal contract with board monitoring exists between them and no funding or personnel are provided by one to the other. TPRN is an intervention, support, and resource service provided by the TPA and its volunteers to assist pharmacists with their recovery from alcohol and chemical dependency. TPRN does not provide direct rehabilitation services. Although the board allows licensees to choose their own recovery program, TPRN is the only support and advocacy network that the board actively recommends when disciplining pharmacists. For those impaired pharmacists who use TPRN to meet disciplinary requirements from the Board of Pharmacy, TPRN provides periodic reports to the board regarding the pharmacists' progress in their programs.

There is another peer assistance group associated with the HRBs that could be leveraged by the board for all its licensees (pharmacy technicians as well as pharmacists), not just the pharmacists served by TPRN. However, there is no evidence that the board has any involvement with it. The Tennessee Peer Assistance Program (TnPAP) offers consultation, referral, and monitoring for impairments due to the use of drugs or alcohol or for a psychological or physiological condition. Originally established by the Tennessee Nurses Association and placed under the Tennessee Nurses Foundation, TnPAP contracted only with the Board of Nursing. Because of its success and the interest expressed by other professional boards, it embraced other healthcare professionals. It currently partners with seven other state boards and committees under an agreement with the Department of Health and with colleges and universities for students enrolled in a health profession education program.

Recommendation

The Board of Pharmacy should develop a formal disciplinary monitoring system. As promised in the six-month follow-up to the previous audit, the Health Related Boards' new computer system, LARS, should be updated to include monitoring assistance capabilities. In addition, the board should formalize its relationship with the Tennessee Pharmacist Recovery Network and consider also using the Tennessee Peer Assistance Program to provide consultation, referral, and monitoring services to its licensees and itself.

Management's Comment

We concur. We have assigned a staff member to monitor disciplined licensees. Additionally, Board staff along with the Office of General Counsel will recommend to the Board in future disciplinary actions that licensees receiving probation for a violation and be required to reappear before the Board and obtain an Order of Compliance prior to the lifting of such

encumbrance on their license. Related to the peer assistance recovery network, the Board of Pharmacy is currently working on an RFP (Request For Proposal) to formalize the relationship with the Board for peer assistance for licensees in need of such support. Once selected, the Board will monitor the program to ensure that it is providing appropriate consultation, referral, and monitoring services.

Board of Pharmacy – Department of Health, Office of General Counsel – Disciplinary Process Timeliness

Pursuant to Section 63-10-304(f), *Tennessee Code Annotated*, the Board of Pharmacy (board) may take disciplinary action against its licensees by conducting hearings, issuing subpoenas for witnesses and records, revoking or suspending licenses, and issuing orders for violations of statute and rules. Assisting the board's executive director in reviewing inspection results and consumer complaints to determine what will be pursued for disciplinary action are the board's chief inspector/investigator and attorneys and legal staff from the Department of Health's Office of General Counsel. If disciplinary action is pursued, the Office of General Counsel takes control from board staff, opens a case file per licensee (single or multiple allegations), and begins preparing the case to bring before the board for a hearing to determine disciplinary action. It then processes the appropriate orders.

Our audit objective was to determine the timeliness of the disciplinary process resulting from inspections and consumer complaints. The Office of General Counsel has a benchmark of 365 days to close a case it has received from the board's inspectors/investigators. We reviewed all 751 cases opened in calendar years 2013 and 2014, and all cases closed in calendar year 2014. We found that the Office of General Counsel was meeting its benchmark.

Results of Other Audit Work

1. With the exception of Board of Pharmacy cases alleging gross negligence, the Office of General Counsel is meeting its disciplinary case closure benchmark, but shortening the benchmark or having different benchmarks for different types of cases would improve staff efficiency and effectiveness

We reviewed all 751 cases opened in calendar years 2013 and 2014 and all cases closed in calendar year 2014. As the following two tables show, almost all the cases (allegations) are in three areas: gross negligence/incompetence, misconduct, and unlicensed practice. The Office of General Counsel exceeds its 365-day benchmark for closure in only one of those areas—gross negligence/incompetence. Other allegation types take significantly fewer days to close.

Cases Opened in 2013 & 2014 by Allegation Type

Allegation	Count	Percentage
Criminal Conviction	1	0.1%
Denial of Claim	2	0.3%
Disciplined - Another State	21	2.8%
Fiduciary/Theft	1	0.1%
Fraud/Forgery	1	0.1%
Gross Negligence/Incompetence	156	20.8%
Inspection Violations	43	5.7%
Medical Necessity	1	0.1%
Misappropriations	1	0.1%
Misconduct	327	43.5%
Other	53	7.1%
Practice - Expired/Inactive License	9	1.2%
Unfair Discrimination	1	0.1%
Unlicensed Practice	134	17.8%
Total	**751**	**100.0%**

Cases Closed in 2014 by Allegation Type

Allegation	Count	Percentage	Average Duration
Criminal Conviction	1	0.2%	96
Disciplined - Another State	9	2.1%	222
Fiduciary/Theft	1	0.2%	84
Gross Negligence/Incompetence	100	23.3%	407
Inspection Violations	19	4.4%	116
Medical Necessity	1	0.2%	12
Misconduct	196	45.6%	163
Other	21	4.9%	126
Practice - Expired/Inactive License	3	0.7%	161
Unfair Discrimination	1	0.2%	32
Unlicensed Practice	78	18.1%	215
Total	**430**	**100.0%**	225

The Office of General Counsel stated it is

> in the process of re-visiting these OGC benchmarks and . . . considering different benchmarks for different case types. Some cases certainly can be and are completed in less time; some may require more time. Of course, there are various factors outside of the control of the Office of General Counsel which impact our benchmark success—such as continuances granted by the Administrative Law Judge assigned by the Secretary of State's office.

We recommend that the Office of General Counsel pursue its reconsideration of its single benchmark in favor of multiple benchmarks based on type of case or complexity, etc. Efforts

like this will keep staff and resources focused and productive, providing for a more efficient and effective operation.

CONTROLLED SUBSTANCE DATABASE COMMITTEE AND DATABASE MONITORING PROGRAM

The Tennessee Prescription Safety Act of 2012, codified in Title 53, Section 10, Chapter 3, creates the Controlled Substance Database Committee (committee) and the Controlled Substance Database (database) and requires all prescribers in the state who are registered with the U.S. Drug Enforcement Agency who prescribe controlled substances and dispensers who provide direct care to patients for more than 15 calendar days a year to register with the database. Licensed veterinarians who never prescribe a controlled substance in an amount intended to treat a non-human patient for more than 48 hours are not required to register with the database.

According to Section 53-10-303(h)(1,4), *Tennessee Code Annotated*, the committee examines "database information to identify unusual patterns of prescribing and dispensing controlled substances that appear to be higher than normal, taking into account the particular specialty, circumstances, patient-type or location of the prescriber or dispenser." If a pharmacist or prescriber is found to have an unusually high pattern of dispensing or prescribing controlled substances that is not explained by other factors, the committee is to refer the person either to the chief investigator of the Board of Pharmacy (board) or the Health Related Boards' Bureau of Investigation. The investigators report back to the committee with the results and, if a pharmacist or prescriber is found to have no explainable reason for their unusually high pattern of prescribing or dispensing controlled substances, the investigator reports that the case has been referred to a health related board. If an investigator has reason to believe criminal activity has taken place, the investigator is authorized to report such conduct to the appropriate district attorney.

Section 53-10-304(c), *Tennessee Code Annotated*, establishes that the database is administratively attached to the Board of Pharmacy, whose executive director is responsible for determining staffing. The database's purpose is

> to assist in research, statistical analysis, criminal investigations, enforcement of state or federal laws involving controlled substances, and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data as described in this part regarding all controlled substances in Schedules II, III, and IV dispenses in this state, and Schedule V controlled substances identified by the controlled substance data base advisory committee as demonstrating a potential for abuse.[1]

In 2011, the Department of Health entered into a contract with Optimum Technology, Inc., to provide the information technology service that would be the database for the controlled

[1] Although this section of *Tennessee Code Annotated* refers to the database committee as "advisory," that term was dropped from the committee's name by amendment to Section 53-10-303, *Tennessee Code Annotated*, effective January 1, 2013.

substance monitoring database program. The database is intended to collect, maintain, and report information on Schedule II, III, IV, and V controlled substance prescriptions in Tennessee. Subsequent amendments addressed statutory and other revisions regarding prescribers' requirements to check the database before issuing a prescription, increased use of the database, data-sharing between multiple states, enhanced audit capabilities for quality assurance purposes, expanded reporting functions to identify abuse, and upgrading the ability of the database to investigate individuals.

Our objectives were to

- identify any statutory and structural gaps in the Controlled Substance Database monitoring program that potentially limit the database's effectiveness;
- determine the extent to which the database is analyzed and queried to proactively provide information to regulatory boards and law enforcement; and
- determine if appropriate platform, application, and data controls were in place and regularly monitored for the database.

We reviewed statute, rules, and regulations involving the committee and database and the contract with Optimum Technology, which provides and maintains the database, and we interviewed law enforcement, contractor, database monitoring program, and Department of Health staff regarding database analysis, data reliability performed, and contract oversight. We found that some allowed exceptions and procedures (or lack thereof) may weaken the database's effectiveness, little proactive analysis is being performed, and that contract oversight of vendor responsibility for data validity and reliability is weak.

Finding

3. Statutory and structural gaps may limit the effectiveness of the Controlled Substance Database monitoring program and the information it provides

The Tennessee Pharmacy Drug Safety Act of 2012 that created the Controlled Substance Database established certain exemptions to the checking of and reporting to the database for prescribers and dispensers. These instances are defined in Section 53-10-304(d)(1-5), *Tennessee Code Annotated*, which specifies the circumstances under which dispensers (pharmacist, pharmacy, or any healthcare practitioner) are not required to **report** to the database:

- a drug administered directly to a patient;
- drug samples;
- drugs dispensed by a veterinarian for a non-human patient (with an amount limited to a 48-hour supply);
- a narcotic treatment program licensed by the U.S. Drug Enforcement Administration (DEA); and

- drugs dispensed to a patient in the care of a licensed health care facility (amount limited to a 48-hour supply).

Section 53-10-310(e)(5)(A-E), *Tennessee Code Annotated*, states prescribers are not required to **check** the database before prescribing or dispensing one of the controlled substances (opioids or benzodiazepines) or a controlled substance added to the list by the committee if one or more of the following conditions is met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) The committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(C) The controlled substance is prescribed or dispensed to a patient as a non-refillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility;

(D) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill;

(E) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68 or a mental hospital licensed under title 33.

In addition, Section 53-10-310(e)(1-3), *Tennessee Code Annotated,* and program Rules and Regulations 1140-11-.06(1-3) state that there are circumstances in which prescribers and dispensers have to **check** a patient's history before they write or fill a prescription each time, thereby revealing that there are instances when they do not have to check the database:

(1) All prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one of the controlled substances identified in subdivision (e)(3) to a human patient at the beginning of a new episode of treatment and shall check the database for that human patient at least annually when that prescribed controlled substance remains part of the treatment.

(2) Before dispensing, a dispenser shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database if the dispenser is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.

(3) The controlled substances which trigger a check of the database pursuant to subdivision (e)(1) include, but are not limited to, all opioids and benzodiazepines.

These statutory exceptions and gaps do not require all prescribers and dispensers to report all controlled substances dispensed and to check before prescribing/dispensing. This results in an incomplete picture of all medications dispensed and in the medical and pharmacy professions virtually policing themselves on compliance with requirements to report and/or check the database. There are also structural gaps (or how the database and its staff operate) that exist and limit the effectiveness of the Controlled Substance Database monitoring program.

The exemptions generate no documentation and are, therefore, inherently difficult to oversee for proper usage. Neither state law, the board, nor the committee and staff have a method of oversight or enforcement with exemption requirements. The board also does not require its inspectors to check for exemption activity or database reporting and checking requirements as part of their inspections. Noncompliance is discovered by accident via inspection, investigation, complaint, tip, etc. Board staff reported that they were not aware of any instances where a pharmacist or pharmacy had regularly and deliberately failed to report controlled substances information to the database, which could result in the loss of one's license and other disciplinary measures. When such incidents had occurred, staff indicated that these were isolated instances and were quickly resolved by contacting the pharmacy in question and addressing the problem.

Recommendation

The General Assembly, the Controlled Substance Database Committee, the Board of Pharmacy, and the Board of Medical Examiners may wish to revise statutes and/or rules to eliminate exemptions and operational gaps or to establish procedures that allow for monitoring and oversight of approved and documented exceptions and compliance with reporting and checking requirements. This will mitigate potential issues that may limit the database's effectiveness.

Management's Comment

We concur. The statutory exemptions and "gaps" do not require all prescribers and dispensers to report all controlled substances dispensed and to check before prescribing/dispensing. The CSMD (Controlled Substance Monitoring Database) is working with the department to assess resources that will enable us to better determine the prescribers and dispensers who fail to comply with the current requirements of the law. We will continue to provide the most useful information possible within the parameters of the law.

Finding

4. Staff of the Controlled Substance Database monitoring program and the Department of Health do not proactively analyze the database to provide information to health regulatory boards and law enforcement

According to Section 53-10-303(h)(1,4), *Tennessee Code Annotated*, the Controlled Substance Database Committee (committee) examines the Controlled Substance Database (database) to identify unusually high patterns of prescribing and dispensing and to refer pharmacists or prescribers found to have these patterns to Board of Pharmacy or Health Related Boards' investigators. If an investigator has reason to believe criminal activity has taken place, the investigator is authorized to report such conduct to the appropriate district attorney.

Per Section 53-10-304(b-c), the committee also makes sure the database monitoring program assists in research, statistical analysis, criminal investigations, enforcement of state and federal laws involving controlled substances, and the education of healthcare practitioners concerning patients who may require counseling or intervention for substance abuse.

There are only two proactive analyses, as opposed to reactive enquiries and analyses, performed by monitoring program staff. Staff compile an annual "Top 50 Prescribers" list, as required by statute, which identifies those in Tennessee writing prescriptions for the highest amounts of opioids and benzodiazepines. Staff notify individuals that they are on the list and are required to respond in writing with an explanation of their prescribing practices. Staff also produce an annual report to the General Assembly on the aggregate prescribing and dispensing trends based on the database. In addition, the report includes annual statistics on how prescribers, dispensers, and law enforcement agencies are using the database.

Program staff indicate that the database is not commonly used to initiate an investigation of a prescriber, but they do refer practitioners to the Bureau of Investigations or Pharmacy Board investigators if they inadvertently find suspicious activity. They do not proactively query the database, searching for patients that may be "doctor-shopping" or specific practitioners with unusual prescribing or dispensing patterns. Rather, staff use information from the database more often to support an action against a practitioner identified in a complaint. Program staff also work with the Office of General Counsel for the Health Related Boards to determine if action should be taken against a prescriber whose name appears on the Top 50 list. The decision to refer a practitioner to a board for disciplinary action is based on a number of factors including whether or not a case is currently pending against the practitioner, past complaint history, and whether or not the practitioner's appearance on the list is explainable and justifiable. The Office of General Counsel indicates that the database is not used to refer possible illegal prescribing practices to law enforcement authorities, except in cases of unlicensed practice.

The Department of Health has obtained a grant from the Centers for Disease Control and Prevention that will provide additional funding to refine and build software capability to enhance the Controlled Substance Database monitoring program's efforts to proactively identify practitioners who prescribe large amounts of controlled substances. This capability has the

potential to assist investigators for the Health Related Boards to customize searches for problem practitioners.

Recommendation

The staff of the Controlled Substance Database monitoring program and the Department of Health should initiate regular analyses of both prescribing and dispensing patterns. The Top 50 Prescribers list is a good tool to identify overprescribing, but there is no such comparable report for dispensing patterns. In order to utilize the database to its fullest potential, program staff should strive to perform additional proactive analyses of prescribing and dispensing patterns throughout the state. Program staff should also explore whether it is feasible to utilize the database to proactively identify practitioners with unusual prescribing and dispensing patterns and refer practitioners to their respective boards for follow-up.

Management's Comment

We agree that there are opportunities to perform more proactive analysis of the database. We have worked for the last year to build a new proactive surveillance system to rapidly create comprehensive patient, prescriber, and dispenser profiles. The patient view provides a risk profile consisting of prescription, hospital discharge, claims, vital statistics, and other relevant data as configured by the end user. The intent of gathering this compressive evidence base is to drive early intervention including education and treatment. The prescriber and dispenser views are specifically aimed at fulfilling our responsibility in TCA to perform regular analyses (surveillance) by uncovering prescribing and dispensing patterns statewide. This new tool migrates these processes away from the current ad-hoc, labor intensive, manual processes which typically takes days to perform, towards a near real-time solution, providing instant results, upon which interventions may be based.

Over the course of the last year, this infrastructure has been realized. We retained the services of a well-regarded outside analytics and visualization group, and now have successfully deployed the new interactive surveillance solution utilizing mirrored, obfuscated CSMD data. We anticipate this innovative new system to be available for use by our board investigators and CSMD staff using full CSMD data within the next two months.

We concur that T.C.A. § 53-10-303(h) authorizes, though it does not mandate, TDH investigators report criminal activity to law enforcement. TDH is dedicated to growing relationships with law enforcement agencies, and communications between TDH's Office of General Council and other agencies on cases relating to prescription drugs have increased. TDH investigators often do attempt to coordinate investigative efforts with law enforcement when possible.

In proactively supporting collaboration between agencies, TDH participated in a roundtable discussion in Spring 2015 where key players from both state and federal agencies, including the Tennessee Bureau of Investigations, Drug Enforcement Administration, Department of Veteran's Affairs Office of Inspector General, the U.S. Attorney's Office and the

Department of Justice, met to discuss strategic partnerships and raise awareness of each agency's efforts to combat Tennessee's prescription drug epidemic. The representatives of these federal agencies also explained the various legal and strategic hurdles that occasionally hinder complete transparency. Following this meeting, TDH actively maintains dialogue with these agencies in efforts to continue education related to health care providers' potential criminal conduct.

In addition to continued efforts to strengthen these alliances, TDH is actively involved in prescriber education across the state and strives to include law enforcement representatives in each of these seminars. During 2015, TDH will host a series of five regional symposia designed to educate attendees on the Controlled Substance Monitoring Database (CSMD), pain clinic laws, overdose deaths, neonatal abstinence syndrome, and the chronic pain guidelines. We have completed four of the five symposia, and the Tennessee Bureau of Investigation has actively participated in two of the four symposia and may participate in the one held in Nashville on October 15, 2015, depending on scheduling issues.

By fostering partnerships with varying law enforcement agencies, TDH is increasing sensitivity and awareness to criminal activity and remains dedicated to using these partnerships to end the prescription drug epidemic.

Finding

5. Program staff and the Department of Health do not monitor the vendor that provides and maintains the Controlled Substance Database for compliance with contract requirements regarding data controls for ensuring validity and reliability, though it appears the vendor does have such controls in place

Controlled Substance Database monitoring program staff indicate that prescription and other information entered in the database is only as accurate as what is entered by prescribers and pharmacists or their staff who fill the prescriptions. Staff perform data reliability and validation checks irregularly and by accident as part of their day-to-day usage of the database and contact with healthcare providers. As listed in its contract, Optimum Technology, Inc., regularly conducts scheduled reviews to ensure the database's built-in controls and operator controls are performing adequately. Data cleansing is also done on a frequent basis. The Secure Application Development Guide, Attachment 3 of the contract, lays out the details in areas such as input and data validation, internal processing controls, and message authentication. We have no evidence that program or Department of Health staff monitor Optimum for contract compliance regarding ensuring the validity and reliability of the system and its data.

Recommendation

The Department of Health's Director of the Office of Information Technology Services, the Director of the Controlled Substance Database monitoring program, and the Executive Director of the Board of Pharmacy should develop processes and procedures, with appropriate documentation, that ensure the vendor responsible for providing and maintaining the controlled substance database complies with the terms of Attachment 3, Secure Application Development

Guide, of their contract, thereby providing reasonable assurance of the validity and reliability of the data in the Controlled Substance Database.

Management's Comment

We concur. Contract oversight of vendor responsibility for data validity and reliability is an opportunity for the Department of Health's Chief Information Officer, the Director of the Controlled Substance Database monitoring program, and the Executive Director of the Board of Pharmacy to improve by developing formal processes and procedures, with appropriate documentation, that ensure the vendor responsible for providing and maintaining the controlled substance database complies with the terms of the contract. We are currently working with the department to assess needs and any limitations in maximizing improvements in this area. As needs are identified, we are committed to addressing them as soon as practical.

ADMINISTRATIVE ISSUES

Our audit objectives were to

- determine if board operations, meetings, and membership met key statutory requirements and were consistent with other best practices;
- evaluate the board's expenses in recent fiscal years and its ability to remain self-sufficient as required by state law;
- determine if the board had sufficient authority to pass legal and investigative costs on to the disciplined licensee, and if so, to what extent they consistently did so; and
- determine if there were exceptions to the statutory per diem reimbursement for board members and the reasons for those exceptions.

Finding

6. The Board of Pharmacy has no written policies or procedures for licensing, inspection, investigations, or the imposition of disciplinary actions and penalties that ensure staff and board members conduct business in a timely, consistent, and equitable manner

The Board of Pharmacy (board) has no written policies and procedures governing the office's day-to-day operations or board operations. There are no operational policies and procedures detailing how the board will fulfill its statutory duties and how staff are to fulfill day-to-day duties such as

- processing initial and renewal applications for licensure of pharmacists, pharmacy technicians, pharmacies, manufacturers, wholesalers, distributers, and sterile compounders and keying information into the computer system;

- maintaining the official record of licensure, ensuring licensees have official documentation of licensure, and maintaining the public online records of board licensees;
- performing continuing education audits;
- inspecting pharmacies, manufacturers, wholesalers, distributers, and sterile compounders and maintaining that documentation in electronic form;
- performing intake, record keeping, investigation of, and resolution of complaints;
- providing the board all the necessary information for members to make fully informed decisions; and
- imposing penalties and other disciplinary action upon licensees and monitoring them for compliance before reinstating their licenses.

Without such policies, the board and its staff cannot ensure that duties are fulfilled in a timely, consistent, and equitable manner. Written policies and procedures assist in mitigating the effects of staff and board turnover, potential personal agendas, and potential conflicts of interest.

Recommendation

The executive director, in conjunction with his chief inspector/investigator and board manager, should review the board's business operations and prepare policy and procedures manuals that include descriptions of how those operations are achieved by staff to the level of detail that a new employee can, with minimal assistance, understand how to accomplish a specific operation.

The board should consider, in consultation with the executive director and representatives from the Office of General Counsel, establishing disciplinary guidelines to assist the board in fulfilling its statutory responsibility. These guidelines—for example, a penalty matrix—would assist the board in being more consistent and equitable in its decision-making.

Management's Comment

We concur, in part; and disagree, in part. Prior to the audit, we did not have any written policies or procedures for licensing, inspection, or investigations. We now have detailed policies and procedures for pharmacist investigators detailing accountability and priorities of duties when performing inspections or investigations. We are still developing a policy and procedure manual for office staff, which will clearly outline staff responsibilities regarding licensure and will be used to train new employees and set performance expectations.

With regard to policies regarding the imposition of penalties, we disagree. Board members have a penalty matrix which contains recommended disciplinary actions (both civil

penalties and other mechanisms) for various licensure violations.[2] At the time of the audit, Board staff did not have a copy of this matrix. The matrix will be incorporated, by example, in a board member policy.

Conflict-of-Interest Disclosures

Conflict-of-interest disclosure statements are designed to ensure that the public's interest is protected and those who make key decisions are independent from the other parties involved. Written, annual disclosure of financial interests, prior employment, employment of immediate family members, and other matters that may influence decisions or could give the appearance of influencing decisions helps to ensure that the board is acting on the state's behalf and that members recuse themselves from decision-making as needed.

We obtained and reviewed all of the conflict-of-interest disclosure statements for board members serving during fiscal years 2010 through 2014. We found that, with few exceptions, board members were not filing conflict-of-interest disclosure statements after their first year on the board.

Finding

7. Conflict-of-interest disclosure statements should be filed annually as required by the Health Related Boards' regulations and best practices

Health Related Boards' Policy 302.01 requires board members to sign the Conflict-of-Interest policy initially upon being appointed to the board and annually thereafter. We reviewed all available conflict-of-interest disclosure statements for board members who served during fiscal years 2010 through 2014. We found that (1) the Health Related Boards' staff stated some of the oldest forms were lost, and (2) the current board members had only filed one disclosure statement since the annual requirement went into effect three years ago in 2012.

Recommendation

As required by regulation of the Health Related Boards and as a best practice, conflict-of-interest disclosure statements addressing financial interests, prior employment, employment of family members, and other matters should be completed annually by all board members as a reminder to be aware of actual, potential, and appearances of conflicts of interest. The executive director should ensure that comprehensive conflict-of-interest disclosure statements are received from board members in a timely manner and that such members recuse themselves as warranted. The board should require disclosure statements to be updated if circumstances change before the annual statement is due.

[2] Auditor Comment: Auditors were told that there was an old and unofficial spreadsheet of past penalties imposed that a few board members might have. Auditors did not see evidence of such a document being used by board members or counsel during observed board meetings.

Management's Comment

We concur. Going forward, all board members will sign a conflict-of-interest disclosure statement on the first meeting of each calendar year. These signed statements will be filed annually as required by the Health Related Boards' regulations and best practices. All new board members will be required to sign a conflict-of-interest disclosure statement during the first meeting they attend in their capacity as a member of the board.

Observation

2. There is no minority member of the Board of Pharmacy as intended by statute

Sections 63-10-301(a) and 302(a), *Tennessee Code Annotated*, state that "the board shall consist of seven (7) members, one (1) of whom shall be a consumer," and that "the governor shall strive to ensure that at least one (1) person serving on the board is sixty (60) years of age or older and that one (1) person serving on the board is a member of a racial minority."

We reviewed all Board of Pharmacy (board) meeting minutes from July 1, 2009, through June 30, 2014, to determine whether board meetings and membership met key statutory requirements. Since fiscal years 2010 and through the end of fieldwork in June 2015, board membership has met statutory requirements with the exception that there has not been a minority member of the board.

When the next vacancy occurs on the board, the board's executive director should inform the assistant commissioner of the Division of Health Licensure and Regulation, who should provide the governor's office with a list of recommendations of suitable minority pharmacists and/or private citizens for appointment, depending on the vacancy.

Observation

3. The Board of Pharmacy is not properly including required statements of necessity in meeting minutes and is not filing such statements with the Secretary of State when, to achieve a quorum, members are allowed to tele-participate in meetings

Section 8-44-108, *Tennessee Code Annotated*, requires that, if a physical quorum is not present at a board meeting's location, a determination of the necessity that board members may participate by electronic or other means of communication to achieve a quorum must be made. This determination and a recitation of the facts and circumstances upon which it was made must be included in the minutes of the meeting and filed with the Secretary of State within two days of the board meeting. These requirements are also stated in Policy 405.5 of the Health Related Boards.

We reviewed all Board of Pharmacy (board) meeting minutes from July 1, 2009, through June 30, 2014, to determine whether board meetings and members met key statutory requirements.

During fiscal years 2010 through 2014, the board allowed for teleconferencing to achieve a quorum in four meetings, only one of which reflected a statement of necessity in its minutes. However, even the one statement of necessity referenced in the minutes and filed with the Secretary of State's office did not include the facts and circumstances as required.

Statements of necessity are formally made by the board every time a physical quorum at the board meeting site is not possible and members are allowed to participate by electronic or other means of communication to achieve a quorum. The board should ensure that such statements are filed with the Secretary of State's office within two days of the meeting date.

Observation

4. The Board of Pharmacy may wish to require those requesting waivers to be present at the hearing or available by telephone as it often has questions that require further communication with that individual or entity

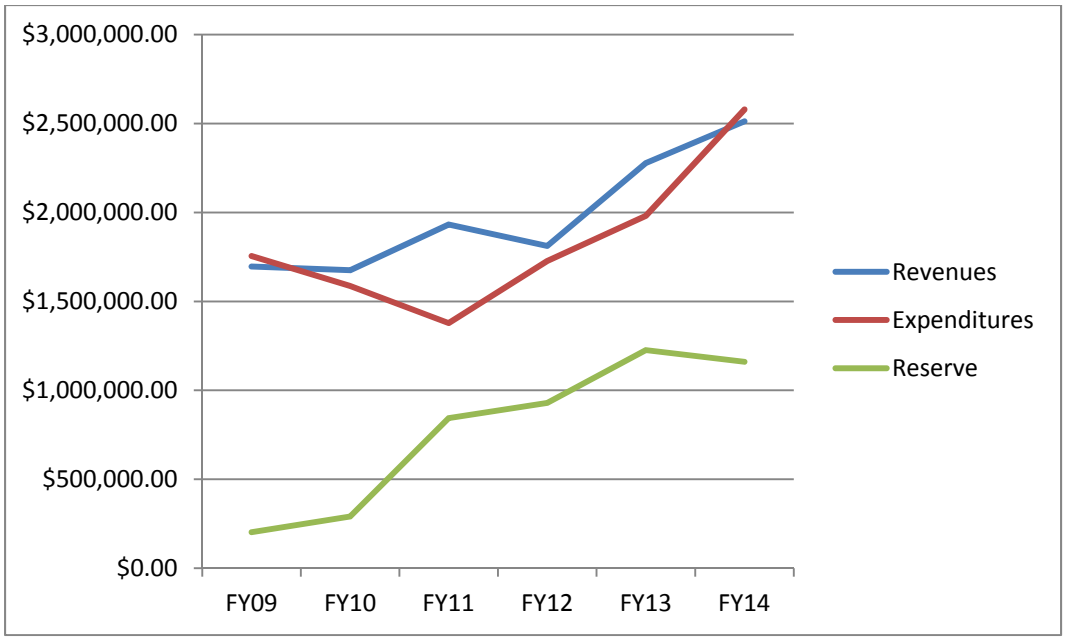
Individuals and facilities requesting waivers from rules, regulations, and licensure requirements are not required to appear in person before the Board of Pharmacy (board) when their requests are considered. Instead, the executive director presents the waiver requests to the board. We observed at board meetings we attended that the board often had questions the executive director could not answer, and the board's decision was delayed until additional information could be gathered. This process is not an efficient use of the board's time. The board should consider requiring those requesting waivers be available in person or by telephone when their request is being considered in the event the board has questions about their situation.

Board Finances

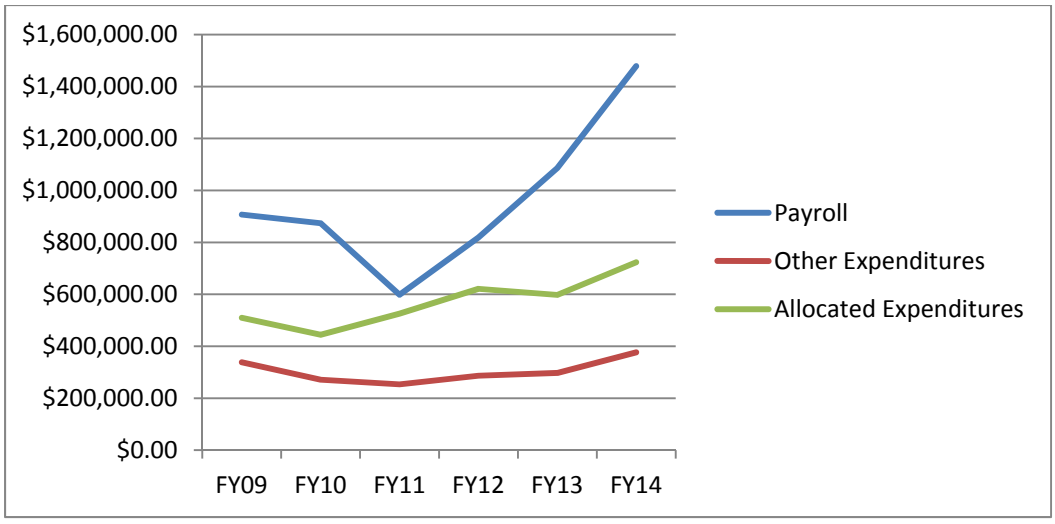
Observation

5. To address its lack of self-sufficiency in fiscal year 2014, the Board of Pharmacy raised fees and implemented, along with the Office of General Counsel, the recovery of legal costs

For fiscal year 2014, the Board of Pharmacy (board) did not collect fees in an amount sufficient to pay operating costs and was, therefore, not self-sufficient as required by Section 4-29-121(a), *Tennessee Code Annotated*. While reserve funds may be used to cover deficits, statute requires boards bring in enough revenue each year to cover expenses without using reserve funds. Expenditures have been rising faster than revenues since fiscal year 2011.



Payroll has been the primary expense that has risen significantly. In October 2013, the board hired three additional inspectors/investigators, for a total of eight, and the next month increased all inspector salaries from $96,288 to $105,912.



Fee Increases

To avoid self-sufficiency issues for a second consecutive year, which triggers a review by a joint Government Operations Committee, the board raised almost all of its fees for fiscal year 2015, with the new fees effective October 2014. With this action, the board and its Health Related Boards financial advisors anticipate just breaking even for fiscal year 2015 because the fees did not take effect at the beginning of the fiscal year. We, as well as the board's Health Related Boards fiscal advisors, anticipate that the new fee structure will result in significant revenue gains over expenditures.

Board of Pharmacy Fee Changes
Effective October 2014

	Previous Fees	New Fees	$ Increase	% Increase
Applicant - pharmacist license exam	$50*	same		
Applicant - reciprocal license/NAPLEX score transfer	$300	same		
Pharmacist registration (initial license)	$96	$125	+$29	+30%
Pharmacist biennial active license renewal	$96	$125	+$29	+30%
Pharmacist biennial inactive license renewal	$48	$63	+$15	+31%
Pharmacy Tech registration	$50	$75	+$25	+50%
Pharmacy Tech biennial active license renewal	$50	$75	+$25	+50%
Biennial registration person/co-owner/operator site where compound/dispense	$168	$300	+$132	+79%
Registration of person/co-owner/operator site where sterile products compounded, packaged, stored, distributed	None	$250	+$250	
Biennial renewal for sterile compounders	None	$250	+$250	
New pharmacy site/change in loci, name, ownership licensure	$168	$300	+$132	+79%
Manufacturers/wholesalers registration	$408	$525	+$117	+29%
Manufacturers/wholesalers biennial license renewal	$408	$525	+$117	+29%
Board's publication of Pharmacy laws, rules, and regulations	$10	amount covering cost of publication & shipping		
Certification of license exam grades	$25	same		
Duplicate or revised pharmacist license wall certificate	$25	same		
Penalty for failure to renew license	$10/mo. delinquent	same		
Failure to provide required notice to director as may be required by board	$50	same		
Biennial renewal fee for those w/license to manufacture/obtain/possess/administer/dispense a controlled substance for purpose of scientific research/chemical analysis/training of detection animals	$60	$100	+$40	+67%

*Plus amount of exam and materials.

Source: Rule 1140-01.10 Fees. *Rules and Regulations*, Secretary of State's Office.

Cost Recovery

We spoke with the Office of General Counsel's representatives who work directly with the board about the legal costs incurred by the board, whether they were being recovered in some way, or if there the possibility of recovering some or all of those costs from disciplined licensees. Section 63-1-144, *Tennessee Code Annotated*, allows for the assessment of investigation and prosecution costs against the license or certificate holder. While costs had not been assessed to disciplined license holders previously, the board began assessing investigative costs around May 2015 as those hours were already being recorded by board investigators. The Office of General Counsel established a prosecution fee policy effective June 1, 2015, that sets out legal hourly rates, and staff will begin keeping track of their time spent on each individual case.

For the board's statements of Actual Revenue and Expenditures for fiscal years 2011 through 2014, see Appendix 3.

Per Diem

Results of Other Audit Work

2. Salary and travel per diem payments were appropriate

Board of Pharmacy (board) members received $100 a day in salary per diem for days conducting board business and reimbursement for travel expenses. We reviewed salary and travel per diem policies and payments made to the board for calendar years 2013 and 2014. We found payments to be appropriate and counseled board staff on paperwork and approvals.

APPENDICES

APPENDIX 1
Title VI and Other Information

The Tennessee Human Rights Commission (THRC) issues a report, *Tennessee Title VI Compliance Program*, (available on its website) that details agencies' federal dollars received, Title VI and other human rights related complaints received, whether the agency Title VI implementation plans were filed timely, and whether THRC findings were taken on agencies. Below are board member and staff demographics, as well as a summary of the information in the latest THRC report for the Department of Health that covers the Board of Pharmacy and Controlled Substance Database Committee as they do not file Title VI compliance reports for themselves.

The Department of Health filed its compliance report on September 6, 2013, making it compliant with the responsibility to file by October 1. For fiscal year 2013, the department reported seven Title VI complaints, five of which they closed that year. No findings were reported. The report with information from fiscal year 2014 is not yet available.

While the Board of Pharmacy does not receive federal funding, the Controlled Substance Database monitoring program that operates under the umbrella of the board may have received federal funds (it is not certain) in a $167,125 grant it received from TennCare's e-Health initiative in fiscal year 2014.

Board of Pharmacy
Ethnicity and Gender
June 2015

	White	Black
Male	4	0
Female	3	0

Board of Pharmacy
Staff Ethnicity and Gender
By Job Position
July 2015

	Male	Female	White	Black
Executive Director	1		1	
Regulatory Board Administrative Manager		1		1
Regulatory Board Administrative Assistant 2		2	1	1
Regulatory Board Administrative Assistant 1		1	1	
Administrative Services Assistant 2		1		1
Administrative Assistant 1		1	1	
Licensing Tech		1		1
Pharmacist 2 Investigator	6	2	8	

Controlled Substance Database Committee
Staff Ethnicity and Gender
By Job Position
July 2015

	Male	Female	White	Black	Asian
Director	1		1		
Epidemiologist		1			1
Statistical Program Specialist 2	1			1	
Statistician 2	1		1		
Licensing Tech	1		1		
Statistical Analyst 2 (vacant)	-	-	-	-	-

APPENDIX 2
Performance Measures Information

As stated in the Tennessee Governmental Accountability Act, "accountability in program performance is vital to effective and efficient delivery of government services, and to maintain public confidence and trust in government." In accordance with this act, all executive branch state agencies are required to submit annually to the Department of Finance and Administration a strategic plan and program performance measures. The Department of Health's priority goals, as reported for the Third Quarter 2015 on the Governor's Customer Focused Government Monthly Results website are as follows for the Board of Pharmacy and the Controlled Substances Database Committee:

Performance Standards and Measures

Performance Standard 1: Reduce prescription drug abuse in Tennessee by improving the ease of use and capabilities of the controlled substances database (CSMD) as a clinical tool.

Purpose of the Goal: Helping to prevent prescription drug abuse protects, promotes, and improves the health of our customers – those currently abusing drugs, those who might abuse drugs in the future, and those indirectly affected.

Measuring the Goal:

	Baseline	**Current**	**Target**
Morphine Equivalents Prescribed in TN (Milligrams, YTD)	9,800,000,000	6,713,091,506	9,310,000,000

APPENDIX 3
Board of Pharmacy
Actual Revenue and Expenditures

Expenditures*	**FY 2010-11**	**FY 2011-12**	**FY 2012-13**	**FY 2013-14**
Salaries	$ 430,504.12	$ 575,650.19	$ 787,136.89	$ 1,064,720.27
Longevity	7,900.00	11,640.00	13,100.00	11,800.00
Overtime	-	-	37.33	-
Benefits	160,170.72	231,495.37	285,973.59	401,985.67
TOTAL PAYROLL	$ 598,574.84	$ 818,785.56	$ 1,086,247.81	$ 1,478,505.94
Travel	$ 83,717.77	$ 69,100.77	$ 86,751.12	$ 119,333.60
Printing & Duplicating	-	1,209.05	44.77	-
Communications	20,505.61	26,362.63	26,528.84	31,819.52
Prof Svc & Dues	21,592.01	50,126.97	17,626.01	20,493.01
Supplies & Materials	4,213.95	2,790.13	1,803.59	1,068.80
Rentals & Insurance	3,726.00	-	995.00	1,125.00
Unclassified	1,600.00	2,400.00	2,400.00	3,600.00
Training of State Employees	3,300.00	1,955.00	8,330.00	7,530.00
Computer Related Items	11,502.77	17,041.17	12,581.82	9,014.38
State Prof Svcs	103,555.59	115,889.37	139,838.51	182,985.30
TOTAL OTHER	$ 253,713.70	$ 286,875.09	$ 296,899.66	$ 376,969.61
TOTAL DIRECT EXP	**$ 852,288.54**	**$ 1,105,660.65**	**$ 1,383,147.47**	**$ 1,855,475.55**
Allocated Expenditures				
Administration	$ 424,251.92	$ 530,426.32	$ 455,000.05	$ 584,414.54
Legal	72,802.08	63,996.37	113,686.75	112,989.53
Cash Office	28,777.26	26,860.32	28,906.77	26,034.04
TOTAL	$ 525,831.26	$ 621,283.01	$ 597,593.57	$ 723,438.11
Total Expenditures	**$ 1,378,119.80**	**$ 1,726,943.66**	**$ 1,980,741.04**	**$ 2,578,913.66**
Fee Revenue	**$ 1,932,020.81**	**$ 1,812,152.59**	**$ 2,277,553.87**	**$ 2,512,777.20**
Current Year Net	**$ 553,901.01**	**$ 85,208.93**	**$ 296,812.83**	**$ (66,136.46)**
Carry-Over/Reserves	**$ 844,197.81**	**$ 929,406.74**	**$ 1,226,219.57**	**$ 1,160,083.11**

*Expenditure line items showing no funds expended in the four years shown were removed.